In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1178V

Filed: August 1, 2018

JONI MARCO,	*	UNPUBLISHED
Petitioner,	*	
v.	*	Onset; Influenza Vaccine; Transverse Myelitis
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Maximillian J. Muller, Esq., Muller Brazil, LLP, Dresher, PA, for petitioner.
Lara A. Englund, Esq., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ONSET[1]

Roth, Special Master:

On October 13, 2015, Joni Marco ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleges that she suffers from "transverse myelitis, a perforated diverticulum, a hernia, a small bowel obstruction, a neurogenic bladder[,] and associated complications" as a result of an influenza ("flu") vaccination she received on October 11, 2013. Petition, ECF No. 1.

[1] Although this ruling has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole ruling will be available to the public. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Respondent postures "the records indicate that petitioner's symptoms started the day before or the day of her vaccination, which would not be consistent with vaccine causation." Resp. Rule 4 Report at 8, ECF No. 18. In response, petitioner requested an onset hearing. ECF No. 36.

An onset hearing was conducted on October 13, 2017. Petitioner, her husband, Dr. Corey Marco, and her daughter, Danielle Marco, testified. *See* Transcript ("Tr."), ECF No. 46. This ruling is intended to clarify the onset of petitioner's symptoms only, and in no way is intended to be interpreted as a finding on causation or entitlement.

Having carefully considered the medical records, affidavits, testimony of the witnesses, and other documentary evidence submitted, I find that petitioner's symptoms began in the late evening of October 11, 2013, the day she received the flu vaccine.

I. Procedural History

Petitioner filed her petition and supporting medical records on October 13, 2015. Petition, Pet. Exs. 1-9, ECF No. 1. This case was initially assigned to Special Master Hamilton-Fieldman.[3] ECF No. 5. Petitioner filed additional medical records and a Statement of Completion in December 2015. Pet. Exs. 10-11, ECF Nos. 11, 14-15. Respondent filed a Rule 4(c) Report on January 26, 2016 stating "[p]etitioner has failed to demonstrate her entitlement to compensation" and therefore "this case should be dismissed." Resp. Rule 4 Report at 8, ECF No. 18.

On May 9, 2016, petitioner filed her affidavit as well as an affidavit from her husband. Pet. Exs. 12-13, ECF No. 20. On June 10, 2016, petitioner filed an expert report from Dr. Lawrence Steinman. Pet. Ex. 14, ECF No. 23. On November 7, 2016, respondent filed an expert report from Dr. Arnold Levinson. Resp. Ex. A, ECF No. 28-29. On April 13, 2017, petitioner filed a supplemental report from Dr. Steinman. Pet. Ex. 15, ECF No. 33.

A status conference was held on July 11, 2017. During the conference, petitioner's expert reports were discussed, particularly concerns that petitioner's expert did not address various inconsistencies in petitioner's medical records or the timing of onset of her alleged symptoms. I also noted that the contemporaneous medical records place the onset of petitioner's symptoms either prior to the date of vaccination or on the same day, as early as twelve hours after the vaccination. Petitioner was ordered to file a status report advising how she would like to proceed and whether testimony clarifying the issue of onset would be appropriate. ECF No. 35.

On July 19, 2017, petitioner filed a status report stating that she would like to proceed with testimony clarifying any factual issues regarding onset prior to submitting additional expert reports. ECF No. 36. An onset hearing was held on October 13, 2017. Following the hearing, a status conference was held on October 17, 2017 at which time I expressed concerns about the inconsistencies between petitioner's medical records, affidavits, and testimony at hearing. Petitioner was ordered to file a status report indicating how she would like to proceed. ECF No. 42.

[3] This case was reassigned to me on January 14, 2016. Notice of Reassignment, ECF No. 17.

On October 17, 2017, unbeknownst to her attorney or respondent's counsel, petitioner mailed a six page letter directly to me. Petitioner's letter included additional facts that petitioner wanted me to consider. She further stated that she was not permitted to properly prepare for her testimony nor was she afforded the opportunity to have her expert testify on causation. She requested another hearing. The letter was filed into the record. ECF No. 44.

A status conference was held on October 31, 2017, during which I discussed the October 17, 2017 letter. The status conference was recorded for the purposes of discussing with counsel the content of that letter. Counsel was advised that a written decision on onset would be issued based on all of the evidence filed in this matter including the medical records, the hearing testimony, the affidavits and the petitioner's letter of October 17, 2017. ECF No. 45. Additional medical records were filed on December 12, 2017. Pet. Exs. 17-18, ECF No. 48. These medical records were considered as well. This matter is now ripe.

II. The Factual Record

In order to determine the onset of, or first manifestation of, petitioner's alleged injuries following the October 11, 2013 influenza vaccine, petitioner's longstanding chronic medical history must be included.[4]

A. Summary of the Relevant Medical History

1. Petitioner's Pre-Vaccination Medical History

Petitioner was under the care of Dr. Sherry L. Braheny, a neurologist, since approximately 1987,[5] for multiple prior head injuries and "many symptoms, including numbness of both hands, weakness of the right arm, recurrent neck pain, cramping of the wrist, arms, shoulders, legs and neck, difficulty with balance, a feeling of dizziness while reading, and itchy feet" and a history of retinopathy[6] following a viral infection. Pet. Ex. 8 at 42, 44.

On September 9, 1992, petitioner presented to Dr. Braheny for evaluation post head injuries in 1975, 1979, and 1983, with continuing positional dizziness, headaches, scalp tenderness, whiplash, memory loss and insomnia. Pet. Ex. 8 at 39-41. She reported increased pain and tenderness over her right temple, as well as the left and right posterior areas of the head with continued dizziness. *Id.* at 38. Dr. Braheny's impression was possible right occipital neuralgia and continued dizziness with uncertain significance. *Id.* Petitioner received an injection of lidocaine and Dr. Braheny recommended a sedimentation rate and an MRI scan. *Id.*

[4] The records of petitioner's prior history are incomplete and contain only random entries. Full records were not provided for the many medical providers.

[5] Dr. Braheny became involved in petitioner's treatment again during her hospitalization following the October 11, 2013 flu vaccine, therefore, her knowledge of petitioner's prior medical history is relevant.

[6] Retinopathy includes either retinosis or retinitis in the eye. *Dorland's Illustrated Medical Dictionary* at 1634 (32nd ed. 2012) ("*Dorland's"*).

On February 20, 1996, petitioner presented to Dr. Braheny with possible reflex sympathetic dystrophy ("RSD")[7] of the left leg and foot with sensory dysesthesias[8] of unknown etiology. Pet. Ex. 8 at 3. She had undergone surgical repair of the left tendon and ligament with complaints that at times it felt like her foot was not part of her. *Id.* at 36-37. Dr. Braheny's impression was left foot pain with unknown etiology, status post left posterior tendon repair, sensory dysesthesia of both hands with unknown etiology, and possible carpel tunnel syndrome. *Id*.

On March 7, 1997, petitioner presented to Dr. Braheny with complaints of overall inflammatory condition with heightened sensitivities, hyper anxiety, and menopause. Pet. Ex. 8 at 31. She complained of left foot pain that began in the summer of 1994. *Id.* at 30-34. She could not walk due to pain, had to wear a left foot brace, and had developed numbness in both hands and feet which had greatly increased over the past three weeks. She was noted to be quite frightened over the significance of the numbness. EMG testing a year before had confirmed RSD. *Id.* at 32. She was worried about memory lapses. Dr. Braheny's overall impression at that time was general inflammatory condition with heightened sensitivity resulting in multiple myalgias[9] and arthralgias.[10] *Id.* at 34. Petitioner was encouraged to lose weight and undergo repeat sedimentation rate. *Id*.

The records further reflect that in 2002, petitioner underwent transvaginal repair of a grade 4 cystocele,[11] repair of rectocele,[12] transvaginal release of adhesions from levator musculature, and repair of the perineum.[13] Pet. Ex. 11 at 121-23. A handwritten note by petitioner contained in the record states that due to further complications, three feet of bowel were removed on approximately December 1, 2004. *Id.* at 122.

At a February 18, 2003 visit, Dr. Braheny documented sensations of nervousness, coldness, racing pulse consistent with dysautonomia,[14] dysesthesias, mild postural tremors, recurrent diffuse

[7] Reflex sympathetic dystrophy syndrome (RSDS), also known as complex regional pain syndrome (CRPS), is a rare disorder of the sympathetic nervous system that is characterized by chronic pain. *Reflex Sympathetic Dystrophy Syndrome*, NATIONAL ORGANIZATION FOR RARE DISORDERS, http://rarediseases.org/rare-diseases/reflex-sympathetic-dystrophy-syndrome (last visited Jul. 10, 2018).

[8] Dysesthesia is the distortion of any sense, especially of that of touch or an unpleasant abnormal sensation produced by normal stimuli. *Dorland's* at 57.

[9] Myalgia is pain in a muscle or muscles. *Dorland's* at 1214.

[10] Arthralgia is pain in a joint. *Dorland's* at 150.

[11] Cystocele is a hernia protrusion of the urinary bladder, usually through the vaginal wall. *Dorland's* at 463.

[12] Rectocele is a hernia protrusion of part of the rectum into the vagina. *Dorland's* at 1608.

[13] Perineum is the region between the thighs, bounded in the female by the vulva and anus, and containing the roots of the external genitalia. *Dorland's* at 1414.

[14] Dysautonomia is a malfunction of the autonomic nervous system. *Dorland's* at 575.

headaches, pelvic pain, back pain, jaw pain, sciatica, and difficulty with concentration. Petitioner was noted to have difficulty walking due to RSD of the left leg and there was a suggestion that she was confused. She had incontinence since her bladder surgery in 2002 and increased headache on a daily basis. Pet. Ex. 8 at 25-26.

Since approximately 2002, petitioner has suffered from diverticulitis as well as rectovaginal fistula,[15] abnormal liver function, pelvic pain, and upper abdominal pain. Pet. Ex. 11 at 45, 145. In April 2004, she was noted to be suffering from a lot of pelvic pain and bowel movements that were hard and painful. *Id*. at 144. She had a right lung nodule unchanged since 1999.[16] *Id*. at 143. On November 12, 2004, she complained of abdominal pain. An ultrasound was normal. *Id*. at 140-44. Fluoroscopy and stomach biopsy performed on December 1, 2004 showed normal cells, common and pancreatic ducts, and scattered inflammatory cells. *Id*. at 132-35. Celiac disease was ruled out in 2005. *Id*. at 148-49.

Records were provided for the years between 2004 and 2009 showing treatment of diverticulitis and fistula. Pet. Ex. 11 at 103-20. A CT on September 9, 2009 of the abdomen and pelvis with intravenous contrast due to lower quadrant pain showed sigmoid diverticulitis without abscess. *Id*. at 115. On November 4, 2009, petitioner's labs showed heavy growth of *klebsiella oxytoca*[17] from taking antibiotics. *Id*. at 93.

Petitioner was hospitalized between December 2 and December 8, 2009, for recurrent lower quadrant pain. Pet. Ex. 11 at 94-110. A discharge summary showed a 61 year old with a 9-year history of rectovaginal fistula. For two month prior to hospitalization she was treated with Augmentin and Flagyl for an episode of acute diverticulitis, which improved then output from the fistula increased. *Id.* at 94-95. CT of the abdomen showed acute diverticulitis with microabscesses. She had recurrent episodes of lower quadrant pain and was hospitalized for acute diverticulitis. Petitioner received two weeks of antibiotics. A CT scan thereafter revealed acute diverticulitis with a 2.5 cm diverticular abscess. *Id*. at 94-110. She had consults with multiple specialists, including infectious disease and colorectal surgery. *Id*. at 97-99, 103-05, 107-08. Petitioner was noted to have persistent, recurrent diverticulitis, with significant inflammation requiring surgical intervention. *Id*. at 98-100, 103-05. A surgical consult noted a need to wait for inflammation to calm down prior to surgery. *Id*. at 100-02. Petitioner was discharged, requiring home health care due to ongoing diverticulitis with abscess, colovaginal fistula, RSD, cervical spinal degenerative disc disease, and hypokalemia.[18] *Id*. at 94-95,107-08. A post-treatment CT of the abdomen on February 26, 2010, showed improvement. *Id*. at 77-78.

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[15] A fistula is an abnormal passage or communication, usually between two internal organs, or leading from the organ to the surface of the body. *Dorland's* at 711. A rectovaginal fistula is a fistula between the rectum and vagina. *Dorland's* at 712.

[16] There are no other records filed about this medical issue.

[17] *Klebsiella oxytoca* is a species of bacteria that is found in the mammalian intestinal tract and human clinical specimens associated with infections of the urinary and respiratory tract. *Dorland's* at 988.

[18] Hypokalemia is an abnormally small concentration of potassium in the blood. *Dorland's* at 903.

Due to increasing lower back pain, petitioner came under the care of Dr. Sanjay Ghosh at the Senta Clinic's Division of Neurological and Spinal Surgery ("Senta Clinic"). Pet. Ex. 6 at 62. On November 9, 2009, petitioner saw Dr. Ghosh for symptomatic lumbar radiculopathy[19] with tenderness in L4-5 due to a grade 1 spondylolisthesis[20] at L4 and L5 with associated lateral recess stenosis.[21] Dr. Ghosh recommended bilateral L5 nerve root blocks and a course of physical therapy. He noted that if petitioner only had a temporary response to his proposed interventions, he would consider a bilateral L4-5 transforaminal lumbar interbody fusion. *Id*. at 107-08. On December 28, 2009, petitioner had an MRI at the direction of Dr. Ghosh for lower back pain which showed an L1-2 central right disc bur complex with mild right foraminal narrowing. *Id*. at 76-77.

Petitioner began seeing Dr. Keith Kortman for epidural steroid injections ("ESIs") in December 2009, with her first injection on December 22, 2009, her second on April 20, 2010, and third on July 27, 2010.[22] Pet Ex. 6 at 95, 102. Petitioner had her fourth injection on October 6, 2010 and noted a band of pain across her right foot and carpal tunnel in both hands.[23] *Id*. at 124.

On April 28, 2010, petitioner's gastroenterologist, Dr. Ali Banaie, wrote a letter on her behalf so that she could travel, stating that petitioner had been hospitalized for peritonitis and abdominal cavity abscess secondary to a rupture of a colon diverticulum in December of 2009.[24] Pet. Ex. 11 at 70. She was critically ill and was maintained on intravenous antibiotics through an

[19] Radiculopathy describes a range of symptoms produced by the pinching of a nerve root in the spinal column. Depending on where the pinched nerve is located along the spine, symptoms include pain, weakness, numbness, and tingling. *Radiculopathy*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/healthlibrary/conditions/nervous_system_disorders/acute_radiculopathies_134,11 (last visited Jul. 17, 2018).

[20] Spondylolisthesis is a condition in which one of the vertebrae slips out of place onto the vertebrae below it. If the vertebrae slips too much, the bone may press on a nerve causing pain. *Spondylolisthesis*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/diseases/10302-spondylolisthesis (last visited Jul. 17, 2018).

[21]Stenosis is a narrowing of any tubular vessel or structural passageway within the body. Lateral recess stenosis is a condition where the narrowing reduces the available space within the foraem of the spinal canal. This may be caused by arthritic overgrowth of the facet joints, degeneration of the disc, and overriding of the facet joints resulting in disc bulging. This loss of space in the foramen can cause squeezing or pinching of the nerve roots. *Lateral Recess Stenosis and Treatment*, THE SPINAL FOUNDATION, http://www.spinal-foundation.org/conditions/lateral-recess-stenosis-and-treatment (last visited Jul. 17, 2018).

[22] Dates of ESIs were identified by Senta Clinic forms within Dr. Corey Marco's records which were filled out by petitioner listing prior injection dates.

[23] According to petitioner's medical records as filed, petitioner had at least 12 ESIs from December 22, 2009 through December 19, 2014.

[24] Dr. Banaie also treated petitioner after her hospitalization in October of 2013.

indwelling PICC line[25] for four months, during which time she was prevented from eating anything other than clear liquids. She had made a good recovery and was stable, though she could eat only soft foods. The PICC line remained in place in case of recurrence during travel requiring medical care. The letter further advised that she would be traveling with prepackaged intravenous antibiotic containers and equipment necessary to deliver the antibiotics through the indwelling PICC line. She also would be traveling with a variety of oral medications for her medical condition of diverticulitis and other maladies. *Id.*

On June 4, 2010, petitioner was noted to have an intestinal abscess and diverticular colon without hemorrhage. Pet. Ex. 11 at 12. She received home infusions from June 4, 2010 through August 2, 2010. *Id*. at 65-66. She was noted to have had chronic diverticulitis for years but was noncompliant with recommendations. She continued to have chronic rectovaginal fistula and sympathetic dystrophy and she was still having pain and nausea. A long discussion about her conditions was had. *Id*. at 62-63. Petitioner suffered a blood clot in her groin in August of 2010. Pet. Ex. 6 at 11.

On January 21, 2011, petitioner received an ESI. Pet. Ex. 6 at 7-8. Petitioner had a follow-up with Dr. Ghosh at the Senta Clinic on April 27, 2011 for her symptomatic lumbar radioculopathy-type symptoms with severe lumbar stenosis at L4-5. Her diverticulosis and diverticulitis were precluding her ability to move forward with spinal surgery. Motor examination at that time was 4/5 on the left foot, 5/5 on the right foot, 4+/5 on the left knee, and 5/5 on the right knee. She had profound loss of pinprick and vibration sense in the left great toe, but such senses were intact in the right and bilateral aspects of the feet. His impression was that petitioner had "significant neurogenic[26] claudication[27] type symptoms" and could not move forward with spinal surgery until her diverticulitis had been addressed via surgery. *Id*. at 98. He also prescribed additional ESIs. *Id*. at 106.

Petitioner received an additional ESI on May 6, 2011 at which time it was noted that her pain was dependent on how well Tramadol worked on that particular day. Pet. Ex. 6 at 9, 104. She was diagnosed with carpal tunnel syndrome, degenerative disc disease, and chronic regional pain syndrome. *Id*. at 103.

On July 29, 2011, petitioner received an ESI. She was taking four to six Tramadol a day for the pain. Petitioner advised that she was moving her youngest daughter into a condo and had been lifting heavy boxes and bending in "unusual positions so [the] pain [was] extreme." Pet. Ex. 6 at 11, 94, 96.

[25] A "PICC line," or peripherally inserted central catheter, is a long catheter introduced through a vein in the arm that is used to administer fluids or medications. *Dorland's* at 307.

[26] Significant neurogenic means originating in the nervous system or from a lesion in the nervous system. *Dorland's* at 1265.

[27] Claudication is also known as limping. *Dorland's* at 369.

On January 25, 2012, petitioner presented to Dr. Ghosh for "progressively worsening lumbar radiculopathy." She was noted to be "handicapped by severe diverticulosis." Pet. Ex. 5 at 2309.

On February 28, 2012, petitioner underwent ESI. She advised that she had been having back, neck, arm, or leg pain for "years and years" from "surgeries, [] child bearing, as well as [an] airplane crash, auto accidents, [and]… compet[ing] in diving, swimming [in] high school, [and] university level." Petitioner was also noted to have started "extreme exercise" and was unsure of whether to continue. Pet. Ex. 6 at 82, 85.

On July 3, 2012, petitioner had an MRI of her lower spine. In comparing the results with her MRI of October 28, 2008, Dr. Ghosh noted that petitioner had a grade VII spondylotic spondylolisthesis at L4-5 with central canal and foraminal stenosis and degenerative discopathy and facet arthrosis at L5-S1 with left foraminal stenosis. Her degenerative discopathy at L1-2, L2-3, and L3-4 remained unchanged. Pet. Ex. 6 at 59-60, 67-68.

On September 14, 2012, petitioner presented to Dr. Ghosh for back pain radiating down the legs. He noted excellent response to the ESIs, but her stenosis had worsened. He would contemplate an L4-5 laminectomy and fusion. Pet. Ex. 5 at 2303-04.

On October 5, 2012, petitioner presented for another ESI and noted her pain was the "worst it ha[d] ever been." Pet. Ex. 6 at 15, 71.

Blood work performed on March 13, 2013 showed high cholesterol. Pet. Ex. 5 at 2291. Petitioner had a chest x-ray for left-sided chest pain in the upper chest on March 20, 2013. The results showed mild degeneration in the AC joint[28] but no acute abnormalities. *Id*. at 2293-94.

On May 7, 2013, petitioner saw Dr. Tomiko Fukuda, an orthopedist, for bilateral foot pain. Pet. Ex. 5 at 2284. Dr. Fukuda noted a "very complex history regarding her feet" and reported that petitioner ambulated with a normal gait but slow cadence. *Id*. at 2284, 2287. Following an x-ray of petitioner's left foot, Dr. Fukuda's impression was that petitioner suffered from hallux rigidus,[29] Morton's neuroma,[30] chronic foot pain, RSD, late effect of tendon injury, and exostosis.[31] *Id*. at 2287-88.

[28] The AC joint is an acronym for the acromioclavicular joint. Craig Hacking et. al., *Acromioclavicular Joint Series*, RADIOPAEDIA, https://radiopaedia.org/articles/acromioclavicular-joint-series (last visited Jul. 16, 2018).

[29] Hallux rigidus is a painful flexion deformity of the great toe in which there is limitation of motion at the metatarsophalangeal joint. *Dorland's* at 818.

[30] Morton's neuroma is a form of foot pain in which there is compression of a branch of the plantar nerve by the metatarsal heads which may lead to formation of a neuroma, or tumor. *Dorland's* at 1181, 1262.

[31] Exostosis is a benign bony growth projecting outward from the surface of a bone. *Dorland's* at 660.

On May 10, 2013, petitioner had an abdominal ultrasound at the direction of her primary care physician, Dr. Corey Marco for reported pelvic pain. There was no evidence of free fluid or pelvic mass. Pet. Ex. 5 at 2281-83.

Petitioner was admitted to Memorial Hermann Hospital on May 17, 2013, for chest pain. A stress ECG and chest x-ray were normal; she was discharged the following day. Pet. Ex. 5 at 2268-79.

In mid-September of 2013, petitioner had a fall through the floor with reported awkward positioning upon landing. Pet. Ex. 4 at 76.[32]

On September 19, 2013, petitioner presented to Dr. Marco, with back pain radiating to her legs. Pet. Ex. 5 at 2208. She had degenerative disc disease of the lumbar spine with spinal stenosis. She required Tramadol on a regular basis to function; the pain radiated down both legs to the level of the knees or further. There was no bowel or bladder incontinence other than Stress Urinary Incontinence ("SUI")[33] from cystocele. Active problems were: candidiasis; esophageal reflux; fatigue; hyperlipidemia; hypertension; hypothyroidism; sore throat and urinary tract infection. *Id*. Physical examination showed decreased range of motion of the lumbosacral spine to 60 degrees of flexion and diminished extension, tenderness over the spinous process of L3-5, and no neurologic deficit. *Id.* at 2209. The plan was to refer her back to the doctor who provided epidural injections in the past. *Id.* at 2208. She was prescribed Amoxicillin 500 mg by mouth three times a day for 10 days for urinary tract infection and sore throat. *Id.* at 2206. Blood work performed on that date showed positive Cyclic Citrullinated Peptide ("CCP") antibodies IgG/IgA[34] and high cholesterol. *Id*. at 2580, 2582.

On October 1, 2013, petitioner had another ESI and noted that she had pain with walking, standing, sitting, laying down, and lifting. Pet. Ex. 6 at 17, 56.

2. Petitioner's Post-Vaccination Medical Records

On October 11, 2013, petitioner presented to Rite Aid and received the allegedly causal flu vaccine.[35] Pet. Ex. 1 at 6.

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[32] This was noted in her hospital record from November of 2013, the notation also noted "no actual landing . . . uncertain clinical significance. Consider factor in spinal cord injury." There were no medical records associated with the fall provided. Pet. Ex. 4 at 76.

[33] Stress urinary incontinence is the failure of voluntary control of the vesical and urethral sphincters, with constant or frequent involuntary urination, due to anatomic displacement that exerts an opening pull on the bladder orifice, as in straining or coughing. *Dorland's* at 928.

[34] Positive results of cyclic citrullinated peptide antibodies indicate a high likelihood of rheumatoid arthritis. *Kelley's Textbook of Rheumatology* 1044-1045 (8th ed. 2009) ("*Kelley's"*).

[35] Petitioner's Exhibit 1 is a billing record for the allegedly causal flu vaccine. There is no actual record for the vaccine.

On October 15, 2013, petitioner presented to Dr. Boris Khamishon at the Neurology and Epilepsy Center. Pet. Ex. 2 at 3. She was a 65 year old woman with a history of chronic lower back pain diagnosed as degenerative disc disease with central canal stenosis. She presented with new onset of weakness in the lower extremities with bowel and bladder incontinence "since four days ago."[36] *Id.* She was convinced that her symptoms were triggered by a dose of Crestor[37] that she took the night before she received the flu vaccine, October 10, 2013. Her symptoms were more pronounced on the left side. Petitioner noted a long history of arthritis affecting both knees, but mostly her left, with pain and swelling. She was diagnosed with RSD years ago in the left extremity. She stated that her symptoms were different from her usual pain in the lower back and legs and were severe and dramatic. She took Percocet and Tramadol for pain. *Id.* Examination revealed very little weakness and some numbness which was noted to be potentially part of the RSD. *Id.* at 3-6. An MRI was ordered. *Id.* at 6.

The following day, October 16, 2013, petitioner presented to the emergency room at Sharp Memorial Hospital ("Sharp") complaining of loss of bowel and bladder control. She came under the care of Dr. Roth. She reported long standing back pain for which she received injections. She reported recent routine lab work that showed high cholesterol for which she took a single Crestor and a day or so later, noticed some band like pain in the upper and lower extremities; the upper extremity pain had gone away. She stated that she then had increasing lower extremity pain, weakness, and difficulty walking. She had no fever, cough, or congestion. She had an overall generalized headache. She stated that she needed a walker to walk which was new for her. She noted irritation of her diverticulitis but this was chronic for her and did not appear to be acute. Pet. Ex. 3 at 221-24. She was admitted to Sharp on that date where she remained until November 3, 2013. *Id*. at 105.

A neurology consult that day, noted acute onset of bilateral sensory motor deficits involving the lower extremities. According to the patient, the symptoms started seven hours after taking Crestor. The event started as numbness involving the right foot which rapidly progressed and involved the left lower extremity up to the entire pelvic area. The event was associated with bilateral lower extremity weakness to the point that she was using a walker for ambulation. She complained of saddle and perineal area numbness with urinary and bowel incontinence. The event was sudden, bilateral, with less severe radicular pain, more on the low back with numbness that was localized to the perianal area, and was symmetric. There was no sensory level involvement on the thoracic area and no spinal focal tenderness. She denied trauma. She had preserved but symmetric hyper-reflexic reflexes, and overall absent ankle jerk on the right side. She had distal paresis of the left lower extremity with foot drop which was less marked on the right. There were

[36] That would place onset the day of the vaccine, October 11, 2013.

[37] Crestor, also known as rosuvastatin calcium, is a prescription drug to reduce cholesterol. *Rosuvastatin Calcium – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE, http://www.pdr.net/drug-summary/Crestor-rosuvastatin-calcium-2318.6051 (last visited Jul. 12, 2018).

no fasciculations,[38] no dysesthesia, and no allodynia.[39] She was referred by the emergency room neurologist for an MRI for possible cauda equina syndrome.[40] The MRI was suggestive of degenerative disc disease and facet changes with severe canal compromise at the L4-5 level. She had cranial nerve involvement and difficulty swallowing, but was otherwise stable. Her history was significant for RSD which was thought to be the result of ciprofloxacin, hypertension and diverticulosis. Pet. Ex. 3 at 128.

Petitioner was noted to be alert and oriented with normal recent and remote memory, fund of knowledge, and fluent and comprehensive speech. Dr. Roth's impression at that time was a constellation of symptoms, including a sudden onset of bilateral sensory motor deficits involving deep tendon reflexes in the lower extremities with associated urinary and bowel incontinency. There was a consideration of conus medullaris syndrome.[41] The plan was to continue sympathetic pain management and consult physical and occupational therapy. No neurosurgical consult was deemed necessary. Pet. Ex. 3 at 128-29.

A neurosurgical consult by Dr. Richard Ostrup took place later that day on October 16, 2013. Pet. Ex. 3 at 124-26. Petitioner was noted to be a 65 year old with back problems dating back a few years with occasional right leg radicular complaints which prompted epidural steroid injections. *Id.* at 124. According to the patient, she had recently been in Texas helping her daughter and after her return developed pain around October 1, 2013 requiring further evaluation and treatment with an epidural steroid injection.

> About 6 days ago, she took a cholesterol pill – Crestor. She states at that [sic] night, she woke up with pain, which was sort of like a band-like pain around her legs, coupled with some incontinence, not only of bladder, but also of stool. She does have a history of rectovaginal fistula. This has been going on for about 6 days.

Id. She apparently saw a neurologist the day before and tests were ordered, but she developed significant leg pain prompting presentation to the emergency room. *Id.* An MRI did not show any acute change to account for her neurologic change of incontinence or bilateral lower extremity pain. *Id.* at 124-25. Her study looked similar to one several years ago. A thoracic study had not

[38] Fasciculations are small local contractions of muscles which are visible through the skin. *Dorland's* at 682.

[39] Allodynia is pain resulting from a non-noxious stimulus to normal skin. *Dorland's* at 51.

[40] Cauda equina syndrome occurs when the nerve roots of the cauda equine are compressed and disrupt motor and sensory function to the lower extremities and bladder. *Cauda Equina Syndrome*, AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS, http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Cauda-Equina-Syndrome (last visited Jun. 29, 2018).

[41] Conus medullaris syndrome is similar to cauda equine syndrome in that it is a complex neurological disorder which presents with symptoms consistent with spinal cord compression and dysfunction due to trauma at the terminal end of the spinal cord known as the conus medullaris. James S. Harrop et. Al., *Conus Medullaris and Cauda Equina Syndrome as a Result of Traumatic Injuries: Management Principles*, 16 NEUROSURGICAL FOCUS 19 (2004).

been done. *Id.* at 125. "On talking with her today, she does move her legs. She walks but she walks with a waddle, which she says is markedly different than her usual gait. She has had some pain in the legs." *Id.* A CT of the head did not show acute issues. Her upper extremity issues appeared to be more carpal tunnel related. *Id.*

Dr. Ostrup further noted that she was resting comfortably in bed and her affect was "quite reasonable." Pet. Ex. 3 at 125. Palpation of her back generated some discomfort in the thoracic and lower spine. *Id.* at 126. She had reasonable strength in her lower extremities. She complained of decreased sensation throughout her legs, beginning about the level of the umbilicus (belly button). There was no definite upper motor neuron findings. Reflexes seemed to be diminished throughout. Dr. Ostrup ordered an MRI of the thoracic spine. *Id.*

The MRI of the thoracic spine performed on October 17, 2013 was normal. Pet. Ex. 3 at 166. A repeat MRI three days later, on October 20, 2013, noted a slightly elongated T2 hyperintensive lesion on the spinal cord at the T10 level. On retrospective review, it was noted that the lesion may have been present on the October 17, 2013 thoracic spine MRI study, but was less apparent. *Id.* The impression was possible transverse myelitis ("TM")[42] with unclear etiology; L4-5 spinal stenosis[43] with no myelopathy[44] was noted on exam. *Id.* at 167, 173.

A urological consult was conducted on October 18, 2013, due to incontinence, noting a history of hysterectomy and vaginal sling surgery in 2003 with post-operative rectovaginal fistula requiring three surgical repairs, including a flap. Pet. Ex. 3 at 121. Petitioner reported that the repairs were unsuccessful. Diverticular disease with recurrent inflammation on antibiotics was also noted. She advised that her last flare was two weeks ago, for which she was taking ciprofloxacin[45]. She took Crestor one week ago and awoke eight hours later with numbness in both legs, swelling in both legs and knees, and total urinary and rectal incontinence. Since then she has developed numbness and paresthesia to the perianal area. She had been wearing pads and using the bathroom once an hour, but had no sensation of feeling full, empty, or of the urine coming out. *Id.* She was adverse to a Foley catheter. *Id.* at 122. She was noted to have an unusual incontinence pattern with decreased sensation and lower extremity weakness. All appeared to stem from her Crestor medication though she had used statins in the past. *Id.* The patient was told to have patience with the hope that sensation would return. Kegel exercises were recommended. *Id.* at 123. A Foley catheter was ultimately placed. *Id.* at 132-33.

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[42] Transverse myelitis is the inflammation of the spinal cord in which there are non-inflammatory lesions of the spinal cord which span the width of the entire cord at a given level. *Dorland's* at 1218.

[43] Spinal stenosis is a narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space. *Dorland's* at 1770.

[44] Myelopathy is any of various function disturbances or pathological changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis. *Dorland's* at 110.

[45] Ciprofloxacin is a broad-spectrum prescription anti-biotic used for many types of inflections. *Ciprofloxacin – Drug Summary*, PRESCRIBERS' DIGITAL REFERENCE, http://www.pdr.net/drug-summary/Ciprofloxacin-Tablets-ciprofloxacin-3144 (last visited Jul. 12, 2018).

On October 21, 2013, Dr. Roth ordered a lumbar puncture performed by Drs. Kortman and Keyvani for suspected transverse myelitis. Pet. Ex. 3 at 186, 724. The cerebrospinal fluid was clear and colorless with a colorless supernatant, 4 red blood cells, 4 nucleated cells with 80% lymphocytes, 20% monocytes, 50 mg/dL of glucose, and 19 mg/dL of protein with testing negative for oligoclonal bands but showing increased myelin basic protein at 22.65 ng/mL. There was no measured IgG synthesis and a normal IgG index with negative HTLV I/II antibodies. Cardiolipin IgA, IgG, and IgM were normal and cultures of CSF were negative for growth.[46] *Id*. at 708-10.

A consult with gastroenterology on October 24, 2013, noted abdominal pain with complicated diverticulitis, long term colovaginal fistula, and long term antibiotic use with surgery discussed previously but refused. The assessment was a 65 year old woman with at least three to four previous episodes of complicated diverticulitis with micro perforation and abscesses. The plan was to calm it down with antibiotics, though surgical intervention would be required at some point. Pet. Ex. 3 at 115.

Examination conducted on October 30, 2013, documented presentation to the hospital due to acute onset of loss of bowel and bladder function, with a lot of chronic complaints including chronic neuropathy over the years but now more pain and discomfort after taking Crestor. Creatine phosphokinase ("CPK")[47] levels were not elevated and she had no muscle pain, only leg numbness. She stated that she lost bladder and bowel function since Thursday[48] and walking became irregular, requiring a walker. A fourteen point review noted multiple medical problems and symptoms of chronic leg pain from RSD with chronic edema. She had chronic fistula, with passage of stool through the vagina according to the patient. She reported a lot of abdominal pain on and off from diverticulitis as well. Pet. Ex. 3 at 109. On examination, she had good reflexes, but stated that her legs were numb and hurt when touched. There was no erythema or warmth, she could move her legs, and walked with a walker. She had decreased sensation and incontinence of stool and urine. *Id.* at 110.

Petitioner was discharged on November 3, 2013 to Kindred Care with a PICC line for TPN (nutrition), IV antibiotics, and a plan for surgery for her diverticulitis and related issues in seven

[46] The results of petitioner's lumbar puncture on October 21, 2013, as summarized, were found in Sharp Memorial Hospital's internal records. The results of the lumbar puncture did not appear in a patient or consultation note by Drs. Roth, Kortman, Keyvani, or other physician at Sharp. Pet. Ex. 3 at 708-12, 723-24. However, Dr. Braheny was forwarded the results of petitioner's lumbar puncture and summarized the findings when petitioner saw her on November 12, 2013. Pet. Ex. 4 at 45.

[47] Creatine phosphokinase (CPK), also known as creatine kinase, is an enzyme that catalyzes the phosphorylation of creatine by ATP to form phosphocreatine. The reaction effectively stores the energy of ATP in muscle and brain tissue and holds the muscle concentration of ATP nearly constant during the initiation of exercise. CPK occurs as 3 isoenzymes, each having two components composed of muscle and brain subunits. Differential determination of isoenzymes is useful for clinical diagnoses. *Dorland's* at 429.

[48] It is unclear what Thursday petitioner was referring to, October 24 or the Thursday prior to her admission which would have been October 10, the day before the flu vaccine. But her reference to difficulty with walking suggests that she was referring to Thursday, October 10.

weeks after all had calmed down. The admission to nursing care noted leg discomfort, weakness, fatigue, incontinence of stool and bladder, and possible TM on MRI. Pet. Ex. 3 at 105-08.

Petitioner subsequently developed acute perforated diverticulitis and on November 10, 2013 was transferred to Grossmont Hospital. Pet. Ex. 8 at 9, 16. On November 11, 2013, she was examined by Dr. Braheny, who had treated petitioner since 1987 for multiple problems relating to various neurological complaints, including recurrent headaches, neuralgia, atypical left lower extremity RSD, dizzy spells, and chronic neck and back pain. Dr. Braheny noted that she had not seen petitioner since 2006, but kept up to date through petitioner's husband, who was also a doctor. Petitioner was transferred to Grossmont Hospital for increasing abdominal pain, fever, recent diverticular rupture, and abdominal abscess. Petitioner provided Dr. Braheny with a history of taking Crestor on October 17, 2013 for the first time[49] to treat dyslipidemia;[50] eight hours later, she noticed a numbness of her right foot as if it were asleep. She tried to stand and had severe cramping, pain and tingling, then became incontinent of urine and bowel. She felt severe burning pain in her legs with weakness and was unable to walk. According to petitioner, her husband sought a second opinion to read an MRI and a lesion was found at T10. According to petitioner, a repeat scan on October 20, 2013, was worse. She continued to have pain in her legs and back with spasm. She was diagnosed with TM. She also developed a ruptured diverticulum with abscesses and was treated conservatively with antibiotics until it calmed down, so she could be scheduled for surgery. *Id*. at 9-21.

Dr. Braheny noted that petitioner was ill appearing, with mild memory deficits for historical details of uncertain significance. She had mild generalized weakness with superimposed paraparesis,[51] which may not have been accurate due to pain in the lower extremity upon manipulation. Definite sensory level could not be determined. Pet. Ex. 8 at 11-12. The impression was sudden numbness, tingling with sharp pain, and weakness of both legs beginning on October 17, 2013, with loss of bowel and bladder control approximately eight hours after taking Crestor. She was unable to walk initially, but was now improved. Neurological examination showed moderate general weakness, "with no clinical evidence of TM." The cord lesion was noted to be of undetermined etiology. *Id.* at 14. Dr. Braheny noted that petitioner had occipital neuralgia[52] in the past. *Id.* at 17.

[49] An earlier record indicates that when petitioner presented to Dr. Khamishon on October 15, 2013, she informed him that she took a dose of Crestor "the night before," which would have been October 14, 2013.

[50] Dyslipidemia is an abnormality in, or abnormal amounts of, lipids and lipoproteins in the blood. *Dorland's* at 578.

[51] Paraparesis is partial paralysis of the lower limbs. *Dorland's* at 1379.

[52] Occipital neuralgia is a condition in which the nerves that run from the top of the spinal cord up through the scalp, called the occipital nerves, are inflamed or injured. *Occipital Neuralgia*, JOHNS HOPKINS MEDICINE, http://www.hopkinsmedicine.org/healthlibrary/conditions/adult/nervous_system_disorders/Occipital_Neuralgia_22,OccipitalNeuralgia (last visited Jul. 10, 2018).

An MRI performed on November 13, 2013, was compared with MRI results from October 17 and October 20, 2013. Signal abnormality was again noted at T11-12.[53] Considerations included TM, subacute combined degeneration, Vitamin B12 deficiency, demyelinating disease, infectious inflammatory etiologies, or sequela of spinal cord infarction. Infectious and inflammatory etiologies were felt to be less likely, unless there were clinical laboratory findings favoring the etiologies. Cord infarction was less likely, as there was no known history of sudden or hyper acute onset of neurological deficits. Pet. Ex. 8 at 47-48.

On November 16, 2013, petitioner had a consult with gastroenterologist, Dr. Matthew Isho, for recurrent attacks of diverticulitis since 2008. Pet. Ex. 9 at 7. Dr. Isho noted that her last attack was in October at Sharp, where CT-guided drainage of an abscess was performed. She developed neurological symptoms at that time, could not walk or feel her legs, and was diagnosed with questionable TM. She was administered steroids and had been on TPN and antibiotics since. *Id*. Dr. Isho's impression was complex diverticulitis. CT scan revealed a possible fistula to the colon. Petitioner had questionable TM and spinal spondylosis.[54] *Id.* at 8.

On November 25, 2013, Dr. Isho performed a low anterior resection with primary anastomosis, small bowel resection, drainage of pelvic abscess, take down and repair of colovaginal fistula, and splenic fissure mobilization with colostomy placed. Pet. Ex. 4 at 55-64.

In a follow-up examination on December 5, 2013, Dr. Braheny added petitioner's surgery of November 25, 2013 to her history. Dr. Braheny noted that her workup included a hazy lesion of the spinal cord at T10. Pet. Ex. 8 at 4. According to Dr. Braheny, this was initially missed, then diagnosed as TM; however, she did not clinically fit a typical picture of TM as she never had sensory level involvement. The loss of bladder and bowel with weakness in the legs could be secondary to the lesion. Other possibilities included spinal cord injury from a fall a month prior, viral or immunological etiology. *Id.* at 6. She had mild memory impairment for some past historical details. Dr. Braheny's impression was continued paraparesis superimposed on generalized weakness of uncertain cause, rule out viral, traumatic or inflammatory cause of spinal lesion at T10-12, which was significantly improving. L4-5 spondylolisthesis with moderately severe central canal stenosis was also noted. Dr. Braheny noted that petitioner had chronic neck pain with C6-7 disc bulge of uncertain clinical significance. She had bilateral carpal tunnel syndrome, hypothyroidism, hypertension, dyslipidemia, past history of occipital neuralgia, anemia, nausea of uncertain etiology, myalgias, arthralgias, and situational anxiety. *Id.* at 7.

On December 10, 2013, Dr. Banaie examined petitioner for persistent nausea suspected to be medication related noting her chronic and recent medical history. Pet. Ex. 11 at 54-57. She continued to have neurological symptoms. An abdominal ultrasound on bowel rest showed elevated liver enzymes, a gallstone, and elevated bilirubin. *Id.* at 54-55. Dr. Banaie's impression was that her persistent nausea was secondary to medication, status post-abdominal surgery, deep vein thrombosis of calf, and questionable spinal cord lesion with paraparesis. *Id.* at 57.

[53] It was previously noted to be at T10.

[54] Spondylosis is a condition in which there is degenerative spinal changes due to osteoarthritis. *Dorland's* at 1754.

An MRI performed on December 18, 2013 showed a resolution of the previously noted spinal cord abnormality in the lower thoracic spine at T10-12 and was thought to reflect resolving spinal cord edema. Pet. Ex. 8 at 46.

On her discharge summary on December 21, 2013, petitioner was noted to have atypical TM with resultant paraparesis, possible neurogenic bladder, L4-5 spondylolisthesis with moderately severe central canal stenosis, complex diverticulitis, ruptured diverticulum, pelvic abscess, partial small bowel obstruction, and colovaginal fistula requiring surgery with primary ileostomy creation. She had persistent nausea, multi drug resistant *e. coli* bacteria, left soleal deep venous thrombosis, status post-inferior vena cava filter placement on October 25, 2013, chronic rectovaginal fistula, persistent alkaline phosphatase elevation partially due to immobilization, anemia, chronic neck pain with mild disc bulge at C6-7, bladder incontinence, atypical RSD of the left lower extremity, chronic arthralgias, depression, anxiety, hyponatremia, mobility, and self-care deficits secondary to the above comorbidities. Petitioner was discharged home to her family. Pet. Ex. 11 at 48-51. An MRI of the thoracic spine performed on June 4, 2014 was normal. Pet. Ex. 3 at 8.

The remainder of the medical records relate to petitioner's ongoing treatment and current medical status and are not relevant for purposes of this onset decision. It is notable that petitioner showed up to hearing in a wheelchair. The reason for wheelchair use at the time of hearing was unclear.

B. Affidavits and Testimony of the Witnesses and other Evidence

1. Affidavit of Joni Marco

The affidavit of Joni Marco was filed on May 9, 2016. Pet. Ex. 12.

Petitioner affirmed that she had a prior history of back pain, radicular symptoms, and diverticulitis. According to petitioner, the symptoms she suffered after the influenza vaccination differed from her prior health concerns in both type and severity. *Id.* at 1. Following receipt of the flu vaccine on October 11, 2013, she had some arm soreness and generalized achiness which she attributed to a normal reaction to the flu vaccination. *Id.*

According to petitioner, late in the evening of October 14, 2013, she experienced pain and weakness in her legs. *Id.* On October 15, 2013, she presented to the neurologist, Dr. Khamishon, with urinary incontinence, bowel incontinence, bilateral leg pain and weakness, and an abnormal gait. An MRI of the lumbar spine was ordered. *Id.* On October 16, 2013 she was admitted to Sharp Memorial Hospital with severe pain, leg discomfort, weakness, incontinence of stool and bladder, and "atony with a dilated bladder."[55] IV steroids were administered and a Foley catheter was

[55] Atony is a lack of normal tone or strength, such as in a muscle deprived of its innervation. *Dorland's* at 173.

placed. *Id.* at 2. While in the hospital, she lost control of her legs, bladder and bowels, and her condition continued to worsen.[56] *Id.*

2. Testimony of Joni Marco

Petitioner is a certified licensed interior designer, set designer, attorney, and part-time manager of her daughter's 501(c)(3) charity. Tr. 8. At the time of her vaccine, October 11, 2013, petitioner represented indigent clients in finding the medical care they needed. Tr. 8.

At the beginning of the hearing, petitioner stated that she wore a Fentanyl patch, which is 10 to 100 times stronger than morphine and 5 to 10 times stronger than heroin and can "clog your mind at times." She was also taking Tramadol for pain, thyroid medication, anti-nausea medication, Robaxin,[57] and an antispasmodic to keep her legs from shaking. Tr. 9. According to petitioner, she takes all of these medications every day, which could affect her ability to answer questions. Tr. 9.

Petitioner testified that, on October 11, 2013, she met her daughter at the Rite Aid later in the day and they both went to the back of the store to get their flu vaccines. She stated that she was asked her age, and it was suggested that she take the flu vaccine for those over the age of 65, so she did. Her husband was supposed to come in for his flu vaccine, but he was running late. Tr. 10-11.

Petitioner recalled that she and her daughter then met her husband at Chili's. She had a history of diverticulosis but had not had problems "for a long time" so she decided to have a "really spicy Mexican dish and it was so spicy when they served it, that I began to drink like crazy because my mouth was on fire." Tr. 11. That night, she was up urinating all night from drinking so much water and had diarrhea from eating food she was not used to. Tr. 11, 37. When asked on cross-examination to clarify whether she was just urinating a lot or wetting her pants, petitioner responded:

> Wow, I was all of that, you know. I couldn't get to the bathroom on time. I was having to go frequently, frequently, frequently. And, of course, I aided the issue by drinking a lot, but my stomach and mouth were on fire, so I had a lot to drink. So I kept drinking because I – my stomach was upset. So, yes, I had to go to the bathroom frequently.

Tr. 39. She remembered being up until 2 or 3 a.m. going to the bathroom. She then awoke on October 12, 2013 around 10:30 a.m. and went to the airport to pick up her other daughter, who

[56] The remainder of petitioner's affidavit speaks of her injuries and damages and will be addressed if appropriate at a later time.

[57] Robaxin, also known as methocarbamol, is a prescription muscle relaxant used as adjunct therapy for acute, painful musculoskeletal conditions. *Methocarbamol – Drug Summary*, PRESCRIBERS' DIGITAL REFERENCE, http://www.pdr.net/drug-summary/Robaxin-Robaxin-750-Tablets-methocarbamol-957 (last visited Jul. 12, 2018).

was coming home. Tr. 11-12. According to petitioner, her arm may have been sore from the vaccine and maybe her body hurt a little bit, but it was the usual from a flu vaccine. Tr. 13.

Petitioner recalled that on Sunday, October 13, 2013, she cleaned all day because she was expecting company that week. Tr. 13. Around dusk, she was going to the family room and saw something on the floor and thought one of the dogs had an accident. According to petitioner, she went to get her husband who looked at it and said it was human stool. She went to the bathroom and checked her underpants and there were "some more little tiny pebbles of stool" in her underpants. According to petitioner, she was shocked that she could pass stool without even knowing it. Tr. 13-14. According to petitioner, "[i]t was totally opposite from what [she] experienced only a couple days before" with the diarrhea from the Mexican food. Tr. 15.

According to petitioner, on Monday, October 14, 2013, she felt like she strained her back. She attributed it to everything she had done the day before, cleaning the house, the patio furniture, being "up on ladders," and felt it came from bending over the wrong way. Her legs "were just kind of pulling and felt funny." Tr. 15-16. According to petitioner, she could not really define the pain, it was like "pressure… and kind of like a weakness almost at the same time," but she did not think much of it. Tr. 16.

Petitioner testified that on Tuesday, October 15, 2013, when she awoke, she had "some weird back pain and leg pain." She felt weak and was dragging her left leg. She felt some pain but felt like she had overextended herself. She called her husband in the office and described the symptoms. He said it sounded neurological and set up an appointment with a friend, Dr. Khamishon. Tr. 17.

Petitioner recalled seeing Dr. Khamishon that day. She explained to Dr. Khamishon that on Friday night, she couldn't stop going to the bathroom with diarrhea and urinating and could not control it, and that morning was the total opposite; she felt like she had to urinate but couldn't. They talked about her back and he suggested an MRI. Tr. 18. Petitioner explained that she now understands the meaning of incontinence: the night of the shot she couldn't stop urinating and maybe leaked a little in her pants, but when she saw Dr. Khamishon, she couldn't go at all, but "her panties were a little wet," which would be incontinence. Tr. 38.

Petitioner recalled that, after her appointment with Dr. Khamishon, she went home and laid down as he suggested. Her husband got her a walker because she couldn't walk. According to petitioner, she had a history of back issues and diverticulosis but this was different. It was a band like pain around her leg, with pressure in her back. She was dragging her leg, and the pain was higher than her usual pain. It felt like a lead ball in her back pulling up and pulling down. Tr. 19-21.

Petitioner remembered waking up at 3 a.m. on October 16, 2013, "screaming in pain." Tr. 21. She couldn't walk, couldn't bend her knees, it was the most intense pain she ever had. Her screaming woke everyone in the house. She wanted to go to the bathroom but couldn't. "And the whole thing was very alarming to me." Later that morning, her husband thought they should go to the emergency room. When she arrived at the emergency room, she tried to answer the doctor's questions. Tr. 21-22. According to petitioner, the emergency room doctor asked when she had

pain, and she asked him, "pain of any kind, any type of pain, when did I first have pain?" Tr. 22. She told him it was when she had the flu vaccine that she had pain that she did not normally have, an "achy flu shot sensation." Tr. 22. She then asked the doctor what day it was, and was told it was the 16th, so she counted backwards on her fingers, "16, 15, 14, 13, 12, 11" and told the doctor she experienced pain six days ago.[58] Tr. 22. Petitioner explained that she based everything on six days, and told the doctor that on the fourth day counting backward, she had "the funny stool in my underpants."[59] Petitioner stated that they spoke about everything including the pain the day before when she saw Dr. Khamishon, "[a]nd I think once he asked if I had the flu shot, but that wasn't important." He asked what medicines she was taking. Then he spoke to her husband for a bit and said due to her level of pain, he would have to admit her. Tr. 22-23.

According to petitioner, upon admission she was catheterized because she couldn't go to the bathroom, and while doing that, they saw stool in her pants, but she couldn't feel it. She was screaming from the pain, and was given "heavy duty pain medications, kept on "heavy duty pain medication" throughout her stay and her family told her she was out of her mind for most of the time. Tr. 23-24.

Petitioner stated that she mentioned the flu vaccine one more time during her admission, but the doctors said that it was irrelevant, so she never mentioned it again. She then stated, "No one knew I had taken the flu shot. And I thought it was irrelevant myself." Tr. 24.

Petitioner was asked about her references to taking Crestor. She stated that her husband brought it home and she thought it would be good for her, but she was afraid to take it unless he was home, so she took it around 6:30 or so Saturday night, October 12, 2013, seven or eight hours after she awoke that day. Tr. 26-27, 30-31. She was asked why the records repeatedly indicate that she had problems seven or eight hours after taking the Crestor. She responded that she never had problems before or after the Crestor and had no idea why her medical records would say that. Tr. 31-32.

Petitioner was then presented with a medical record from October 18, 2013, which stated, "[a]bout six days ago, she took a cholesterol pill, Crestor. She states that at that [sic] night she woke up with pain which was some sort of band like pain around her legs coupled with incontinence not only of bladder but also of stool." Pet. Ex. 3 at 124-26; Tr. 33. Petitioner responded, "I don't know what to say. I took Crestor Saturday night. I didn't wake up that night. I think he's confused. He's mixed up several different things in here." Tr. 33.

Petitioner again used the process of counting backward, stating that the record was written on the 16th, so if you count backward, the flu shot was six days ago on Friday, October 11, 2013 and the Crestor was five days ago, on Saturday, October 12, 2013. Tr. 34. Petitioner added that she was in the hospital in a lot of pain and had no idea where the information in the records came from. Tr. 33-34. Petitioner added that she took the Crestor on Saturday night because she takes all

[58] By petitioner's explanation, she began experiencing pain on Friday, October 11, 2013, the day that she received the flu vaccine.

[59] Accepting petitioner's explanation of counting backwards, the date would be Sunday, October 13, 2013.

of her pills at the same time. She would not have taken the Crestor on Friday, the same day as the flu shot, because she always worries about reactions and would not have taken it unless her husband was home. Tr. 34-35.

Respondent's counsel asked petitioner how she remembered the events she was testifying to. Petitioner stated that she remembered the events because things stick out in your mind, like the stool on Sunday night, and the flu shot before the Mexican dinner, which was so spicy she "paid for it." Tr. 36.

I asked petitioner to again take me through the details from October 11, 2013, until her hospitalization. She stated that on Saturday, October 12, 2013, she picked up her daughter at the airport and was fine until the night of Sunday, October 13, 2013. Tr. 43. I asked her if she had any leg pain while she was cleaning the house on Sunday. She stated that she might have told someone she had pain on Sunday, but she could not remember it that clearly because it wasn't acute enough, but that changed on Monday. Tr. 44.

I asked her if she had been receiving pain injections in her lower back for chronic back pain prior to her flu shot. She stated that she did, once a year, maybe every six months. She testified that she had spinal stenosis at L4-5, but the pain she experienced after the flu vaccine was totally different. Tr. 44-45. Petitioner stated that at first, she thought the pain was from cleaning and just her L4-5 problem, adding:

> Maybe the question of the doctors was describe the pain that you usually have with this pain and maybe I was describing the pain that I had, you know, from the spinal stenosis and I wasn't able to distinguish properly this kind of pain. It all depended on the questions asked me by the various doctors.

Tr. 45. Petitioner submitted that her answers that "seem peculiar" or "not in line with the dates" was because of how the doctors framed their questions, and because she speaks fast, and because some of them had language difficulties. Tr. 46.

I asked petitioner to describe what was happening on Monday, October 14, 2013. She responded that it was not like Tuesday or Wednesday, and she couldn't really define it, but:

> Maybe my leg was dragging a little bit on Monday. Maybe I felt some different kind of pain. But I couldn't say it was so impressive that I couldn't stand it or that I – I mean, they asked me all sorts of questions like you are, is it band-like, is it this, is it that? And sometimes it's just very difficult to describe pain.

Tr. 46. Petitioner could not recall if it was her left leg or her right that was dragging, stating maybe she had sensations in both of them of pain, it was not definitive yet. *Id.*

I asked petitioner if she ever wore a brace on her left foot. She stated that she did years ago, in about 2001. She had ruptured her tendon and after it healed, she was told she had complex

regional pain syndrome – RSD. She was so active that after it healed she never wore the brace. Tr. 47.

I asked petitioner to describe what she was experiencing on Tuesday, October 15, 2013. She stated that was when the sensations really started. She was dragging her leg, but thought she had overextended herself cleaning the house and doing things she had not done in a long time. Tr. 48.

Petitioner reiterated that everything started Sunday night with the stool on the floor, but no pain. There was nothing going on before the shot and nothing going on until Sunday night around 6:30. Tr. 48-49.

The petitioner added that she does not understand how everyone took a different perspective. "I was confused by this whole experience of what was happening to me and I pride myself in being accurate. But I probably was in a great amount of pain once I got into the hospital and maybe my answers were not totally accurate, and for that I apologize." Tr. 50.

3. Petitioner's letter dated October 17, 2017

Following the hearing, petitioner sent a letter directly to me without the knowledge of her attorney. The letter was filed into the record as ECF No. 44. The letter is being considered as an addendum to petitioner's affidavit.

In her letter, petitioner stated that she "was unable to give comprehensive and consistent testimony at my hearing that took place Friday. I understand in evidence that the record speaks for itself and that in the end one has to defer to the record." ECF No. 44 at 2. Petitioner wrote about the "discrepancy of the timeline I gave various doctors during the time that I was panicked, unwell, emotional, and concerned over the incidents that had happened to me." *Id*.

Petitioner wrote that the first question asked of her in the emergency room was "When did I feel any pain?" According to petitioner, she was not asked about "this particular pain" but "when and where did I feel any pain at all." She asked what day it was, and when told it was October 16, 2013, she counted backward on her fingers to the moment that she received the flu shot because her arm hurt afterward, so October 16 was day 1 and October 11 would be day 6. *Id*. at 3. The pain six days before was

> simply to the pain of my shot and not to the case of transverse myelitis and the pain I felt from that condition and then every doctor following that who did not read the notes carefully said that 'she said that her pain symptoms started six days ago' – which was untrue—that was only referring to the flu shot pain!!!!

Id. According to petitioner, the intense pain that brought her to the emergency room started on October 16 at 3 a.m. and continued onward through her illness. *Id.*

In explaining why the October 13, 2013 incident of Sunday was not contained anywhere in the record until the time of hearing, petitioner wrote that her husband explained to her what it meant when the doctors referred to her stool incident as incontinence.

> [I]t was all about who asked the question and how they asked it and to what did I think about to which matter or incident they were referring. That is why there may not actually be the word 'stool' referenced in the report by Dr. Khamishon or the ER doctor. They were simply referencing the word 'incontinence' as all encompassing.

Id.

Petitioner wrote that she would not have taken a flu vaccine if she had symptoms the day of or in the days prior to the vaccine. According to petitioner, the literature is clear that you don't receive a flu shot when you are sick and she has always been asked that when receiving the flu shot "over the last twenty or so years." *Id*. at 4.

Finally, petitioner wrote

> [I] brought up my experience with diarrhea and running to urinate before I leaked on that Friday and Saturday morning to compare and contrast with the incontinence on Sunday and then on Wednesday that also caused leakage but was just the opposite – my stool was not diarrhea but just hard…--a total contrast of just a few days earlier. Again, there is six days if you try to link them all together even though there was a gap and distinction between the two incidents.

Id. at 5-6.

I do not hold any negative impressions of the petitioner and recognize that this was a very trying and emotional time for her and her family. While I have considered the content of petitioner's letter as part of the evidence in this matter, I remind petitioner that *ex parte* communications with me outside the purview of her attorney is not appropriate. Her action, however, did not negatively affect my determination of the onset of her symptoms.

4. Affidavit of Corey Marco, M.D., J.D.

On May 9, 2016, the affidavit of petitioner's husband, Corey Marco, was filed. Pet. Ex. 13. According to Dr. Marco, petitioner received a flu vaccine on October 11, 2013, after which she complained of soreness and pain in her right arm. Pet. Ex. 13 at 1.

Dr. Marco stated that, he and petitioner went out for dinner the night of her vaccine. He stated that the meal was very spicy and petitioner complained of diarrhea afterwards. She also urinated during the night but he assumed this was due to the amount of water she drank to "quell the spiciness of her food." *Id.* at 2.

According to Dr. Marco, on the morning of October 15, 2013, petitioner awoke with bladder and bowel incontinence and unsteady gait. They went to Dr. Khamishon that day for bilateral leg weakness and urinary and bowel incontinence. *Id.*

Dr. Marco testified that on Wednesday October 16, 2013, petitioner was admitted to the hospital where she continued to receive treatment for symptoms of transverse myelitis, perforated diverticulum, and a myriad of complications through April 29, 2015.[60] *Id.*

5. Testimony of Corey Marco, M.D., J.D.

Dr. Marco is both a doctor and an attorney. Tr. 53. As of the date of the hearing, he had retired from the practice of medicine after 50 years and was practicing law. Tr. 54. Dr. Marco and petitioner have been married for 46 years. He has also been her primary care provider for the past 46 years. Tr. 54.

Dr. Marco stated that October 11, 2013, was a very busy day in his office because it was flu season and he was running late. He was supposed to meet his wife and daughter at the pharmacy two blocks away for influenza vaccines and then proceed to their dinner reservation. Their youngest daughter was coming home the next day and the week had been busy at work and at home trying to straighten things up. He was tired and recalled only wanting to go to dinner. He remembered the pharmacy because "my wife tends to be very dramatic and bubbly and overflowing sort of, and she had discovered there was a new flu shot, a quadrivalent shot. And she was trying to entice me to get that." Dr. Marco stated that he just wanted to go to dinner, which was what they did. It was a very relaxing dinner in one of their favorite restaurants. Tr. 54-56.

According to Dr. Marco, prior to petitioner's October 11, 2013 vaccine, she had complaints but they were her usual complaints, nothing out of the ordinary. Tr. 56.

Dr. Marco did not recall much of October 12, 2013, because it was a Saturday and he worked six days a week. Saturday is his short day, in which he had office hours from 7 a.m. to noon. He would have left that morning before petitioner got up. Tr. 56. He did recall asking her why she was up during the night and he thinks she had stomach problems, diarrhea and was urinating a lot. Tr. 56-57. He recalled being a little happy and excited that his youngest child was coming home, but nothing unusual about that day. Tr. 57.

Dr. Marco was asked why in his affidavit he mentioned his wife's urination the night of October 11, 2013. He responded that it was not terribly significant, it was just not petitioner's habit to get up at night. Tr. 72-73.

According to Dr. Marco, Sunday was a "crisis." It was around dusk, and he was with his two daughters in the house when petitioner came in and said there's poop on the family room floor.

[60] The remainder of the affidavit discussed petitioner's injuries and how they have affected her and Dr. Marco which will be addressed at a later date when appropriate.

> And I remember ultimately we were trying to figure out where the poop came from and we discovered it came from my wife. That raised a crisis for the four of us because my wife was horrified, and she was sort of stricken with this realization that she had pooped in her pants, and there was more in her pants. And I think she was just plain horrified. And that was – that was just a bad time for us.

Tr. 57-58.

Dr. Marco stated that Monday, October 13, 2013, was a better day. Petitioner had been complaining about her back and her leg but they "chalked it up to the fact that she had done a lot of cleaning." Tr. 58. They did not have a lot of interaction during the day because Dr. Marco gets to his office by 6 a.m. Tr. 58. When he got home that night, petitioner had complaints but "my wife often had complaints." Tr. 58. According to Dr. Marco, as her primary care physician and her husband, he knew she had spinal stenosis and significant degenerative disease of the lumbar spine. When she did too much, she would have complaints. She complained a bit more on Monday and he was "scratching his head" because there was poop on the floor the night before and Monday she was complaining of a bit more back and leg pain but he did not make much of it. Tr. 58-59.

Dr. Marco testified that he will never forget Tuesday, October 15, 2013. In 50 years of practice, he never cancelled a patient until that Tuesday. He does not recall what time petitioner called him, but she stated that she could not walk, could not get out of bed, was dragging her feet, and was in way more pain than the day before. Tr. 59. He stated that he thought to himself, there's "poop on Sunday night in her pants without explanation, we've got pain that's more than she usually complains about, and now she's dragging her leg and she can't walk." Tr. 59. Dr. Marco stated that when he got home, his wife could walk but "[he] didn't recognize it as a walk. She looked like a duck. She walked like a duck. And it looked painful and she was crying in pain. So - - I'll never forget that day. That was a very worrisome day and I, frankly, didn't know what to do." Tr. 60. According to Dr. Marco, he called Dr. Khamishon, the neurologist that he usually refers to, and begged him to see petitioner. Dr. Khamishon cancelled some patients to see her. Dr. Marco, with the help of his daughters, got petitioner into the car and drove her to Dr. Khamishon. Tr. 60-61.

Once at Dr. Khamishon's office, Dr. Marco provided petitioner's medical history, her back problems, and the Sunday night bowel incontinence incident, stating to Dr. Khamishon that "when we looked in her underwear on Sunday – Sunday night, her underwear was wet as well." Tr. 61. According to Dr. Marco, petitioner certainly had bowel incontinence and he "felt she had some urinary incontinence as well on October 13th." Tr. 73-74. He added that he was not around the morning of October 15, 2013, so he did not know if she awoke that morning with a bowel movement or urine in her pants, but his focus was her waddling like duck when he got home. Tr. 74. Dr. Marco stated that after Dr. Khamishon examined petitioner, he said that he did not know what was going on with her but it could be related to her back, so he ordered an MRI. Tr. 62.

Dr. Marco testified that Wednesday was the worst, "the day in infamy for us." Tr. 62. They went to bed Tuesday night and at about 3 a.m., petitioner awoke screaming in pain. He had never had anyone wake him up screaming in pain. Petitioner was in "dire straits," and could not walk. She woke everyone up "shrieking in pain, I can't – I can't get it out of my mind." Tr. 62-63.

According to Dr. Marco, it was 3:00 or 4:00 in the morning, and "I'm a physician and I didn't know what to do for her." The family debated which emergency room to take petitioner and decided to drive to Sharp Memorial Hospital, 15 miles away, not the closest hospital near them. They arrived early morning, around 8 or 9.[61] Tr. 63-64.

Dr. Marco stated that petitioner was admitted to the hospital and they did an MRI that showed her usual back problems. Tr. 64. She was begging for pain medication and they gave it to her. Tr. 64. According to Dr. Marco, the admitting doctor was his friend, Dr. Roth, and he was arguing with him about the amount of pain medication that petitioner was given stating that pain medication constipates her and he could not tell whether she was screaming from pain in her back, leg, or from constipation. Tr. 65. Dr. Marco added that petitioner "gets looney" on medicines and her thinking was clouded and confused. "I kept saying to myself, I don't know if they're getting a clear picture here. But it wasn't my job. I was trying not to be a physician, but to be a husband. And so I'm sitting there listening to them taking her history and I'm not so sure she was a good historian." Tr. 65

When questioned about the references to Crestor in the record, Dr. Marco stated when petitioner took Lipitor she had "all kinds of pain, muscle pain, which is – you know, they're notorious for causing that as their side effect." Tr. 66. He had gotten samples of Crestor and brought it home Friday night. Petitioner wanted to try it and he had reminded her of the issues with Lipitor, but she wanted to try it anyway. They discussed it and she decided to take it Saturday night when he was home in case she had a reaction. Tr. 66-67.

Dr. Marco was shown Dr. Khamishon's record for October 15, 2013, which documented that petitioner took Crestor four days ago (on October 11, 2013). Pet. Ex. 2 at 3. Dr. Marco responded "I can guarantee you that she did not" take the Crestor on October 11, 2013. He then added that he recalled her telling Dr. Khamishon and the other doctors about the Crestor and "that I argued with her every time she said it because I said, that is ridiculous, it had nothing to do with the Crestor. Whatever's happening to you now, this pain, your inability to walk and drag your leg, that's ridiculous for you to – to associate that with Crestor." Tr. 69. According to Dr. Marco, he had conversations with every one of petitioner's consulting doctors. "I talked to Dr. Roth about it; I talked with Dr. – the ER doctor about it; I talked with Dr. Ostrup about it. They all agreed with me. I said this is irrelevant. I can recall several discussions about the Crestor." Tr. 69-70.

When asked how he remembered all of the details that he testified to, Dr. Marco stated

> [T]here are three days in my 46 year marriage with my life with my wife that I will never forget. They're stuck there. They're vivid. I can remember every circumstance. The night that she pooped in her pants, horrified; the morning that she called me to [sic] in my office and I got scared about what was happening to her, Tuesday in the morning when I cancelled my afternoon; and Wednesday morning when we woke up with the screaming.

Tr. 70-71.

[61] ER record says 9:15 a.m. Pet. Ex. 3 at 21.

Respondent's counsel then asked Dr. Marco why the incident on Sunday night October 13, 2013, was not described in his affidavit. Dr. Marco responded, "I could have written this better. Had I written it better, I would have said, I was aware that she had had bowel incontinence on the 13th and I believe she may have had—I don't remember exactly, but she may have had it subsequently on the 15th as well." Tr. 74-75. Respondent's counsel pointed out to Dr. Marco that he was a doctor describing the events of the onset of his wife's condition in an affidavit, and questioned how he failed to include this very unusual and significant event on October 13, 2013. Dr. Marco responded, "Of the evening of the 13th? I'm saying is that that is what I'm referring to here and perhaps should have written this affidavit more specifically and more emphatically about the evening of the 13th." Tr. 75-76.

Dr. Marco confirmed that he reviewed the affidavit before he signed it and stated that it was true and accurate to the best of his recollection when he signed it in 2016. Tr. 76. His counsel tried to redirect him and get him to agree that there was a lot of discussion about the content of his affidavit prior to his signing it, but Dr. Marco would not agree, stating that he had no memory of that. Tr. 76.

6. Testimony of Danielle Marco

Danielle Marco is the youngest daughter of petitioner and Dr. Marco. Tr. 79-80.

According to Ms. Marco, she had come home from medical school in Houston, Texas for the weekend to visit her family on Saturday (which would have been October 12, 2013). Tr. 79-80. She recalled petitioner picking her up at the airport. There were no specific plans for the weekend. Tr. 81.

According to Ms. Marco, nothing specific "jumps out to me during the day on Sunday." Tr. 81. They were cleaning the house. Petitioner was always cleaning so it was not anything out of the ordinary. Tr. 86. Ms. Marco did some homework and thinks they might have watched a movie, "really nothing was out of the ordinary until that night with the poop incident when my mom discovered her stool on the floor, which was pretty shocking. But other than that, it, you know, seemed natural." Tr. 81.

When asked to describe the Sunday night event, Ms. Marco stated that petitioner started getting very excited and yelled for them to come help her and see what was happening. Tr. 82. According to Ms. Marco, petitioner may have called for her dad first, but when they heard the commotion, they went to check it out. Tr. 86. "She seemed pretty embarrassed and ashamed when she figured out it was her own stool, but seemed alarmed, too, and you know, wanted to alert us to this thing that happened." Tr. 82, 87. Ms. Marco believes her dad pointed out that it came from petitioner. Petitioner said she did not feel it, so she was surprised. Tr. 87

According to Ms. Marco, Monday was ordinary; they tried to forget Sunday night and not make a big deal out of it. They were cleaning the house, nothing out of the ordinary. Tr. 82. Petitioner made her usual complaints of aches and pains, joking that she was getting old. According to Ms. Marco, petitioner complained of "some back pain that I think sometimes gave her some leg pain. But nothing—nothing really serious." Tr. 87-88.

According to Ms. Marco, on Tuesday, her mom's normal complaining of getting old was different. She seemed to have a little bit of difficulty walking, some leg stuff going on and seemed worried about the issues she was having. Tr. 83. According to Ms. Marco, her dad booked a neurology appointment. She did not think much of it, and planned to go back to school the next day. Tr. 83. Ms. Marco stated that the appointment was in the afternoon. Her dad is a doctor and had asked a friend who was a neurologist to see petitioner. Tr. 88. After being specifically asked, Ms. Marco added that her dad cancelled patients to come home to take her mom to the doctor which was "a little alarming. But I didn't want to think too much into it until we knew what was happening, I guess." Tr. 89.

According to Ms. Marco, on October 16, 2013, she recalled her mother woke everyone up screaming in pain at around 3 a.m. They decided to take her to the emergency room, but it took some time to get her up and moving, so they did not get her out of the house until around 9:00 a.m. Tr. 83-84.

According to Ms. Marco, they all went to the emergency room. She recalled that they catheterized petitioner and a lot of urine came out, even though she had been complaining that she could not go. They did a gait test because she "was walking very strangely, like a duck." Because of her pain, they started "pretty heavy-duty pain medication right away." Other than that, she does not remember anything else. Tr. 84.

According to Ms. Marco, she recalls these events, because she did not return to school after that. Tr. 85.

III. Legal Framework

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs*., 28 Fed. Cl. 516, 523 (1993); *see Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence."

Cucuras, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Id.*

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as in cases where records are deemed to be incomplete or inaccurate. *See Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."). The Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)); *see, e.g.*, *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Moreover, despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs.*, No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"). In short, "the record as a whole" must be considered. § 13(a).

IV. Discussion and Findings of Fact

The only issue to be addressed at this time is the onset of petitioner's symptoms.[62] Petitioner has the burden of demonstrating the facts necessary for entitlement of an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

[62] There are varying opinions of her treating doctors as to whether or not petitioner had TM and whether her symptoms were related to TM or secondary to trauma or some other medical condition from which she was suffering. Those issues are issues of entitlement and will not be addressed here.

Petitioner alleges that she developed TM, perforated bladder, hernia, small bowel obstruction, neurogenic bladder, and associated complications as a result of a flu vaccine she received on October 11, 2013. Pet. at 1. In general, TM is an autoimmune condition in which inflammation causes damage to the spinal cord. The clinical presentation often develops suddenly and is marked by bladder and bowel problems, a loss of movement in the legs, and numbness.[63]

Petitioner's long standing health problems including chronic diverticulosis, diverticulitis, abscesses, colovaginal fistula, RSD, hypokalemia, cervical spinal degenerative disc disease, and severe symptomatic lumbar radiculopathy with pain radiating down her legs are well documented in the medical records. Pet. Ex. 6 at 98; Pet. Ex. 11 at 62-63, 77-78.

In the month prior to her vaccination, petitioner suffered a fall for which there were no medical records filed or description of injuries, if any, provided. Pet. Ex. 4 at 76. On September 19, 2013, she presented for medical care due to severe back pain radiating down both legs to the level of her knees or further requiring medical intervention. She needed Tramadol on a regular basis in order to function due to chronic pain. She had no bowel or bladder incontinence other than stress urinary incontinence from cystocele. She also had a sore throat and urinary tract infection for which 500 mg of Amoxicillin was prescribed. Pet. Ex. 5 at 2206, 2208. Upon examination, she had limited range of motion of her back and was referred for epidural injections. *Id.* at 2208-09. Blood work on that date showed positive CCP antibodies IgG/IgA, which indicate a likelihood of rheumatoid arthritis, and high cholesterol. *Id*. at 2580, 2582. Petitioner underwent CT guided L4-5 inter laminar epidural corticosteroid injection and bilateral sacroiliac intra-articular corticosteroid injections on October 1, 2013. Pet. Ex. 6 at 17.[64] Petitioner reported a flare of diverticulitis two weeks prior to her hospitalization on October 16, 2013, for which she was taking Cephalexin.[65] Pet. Ex. 3 at 121-22.

In the late afternoon/early evening of October 11, 2013, petitioner presented to Rite Aid and received a flu vaccine. Pet. Ex. 1 at 6. She then went to dinner consuming a spicy Mexican dinner requiring a lot of water, causing her to be up all night with diarrhea and urinating. Tr. 11, 37. When asked to clarify whether she was just urinating a lot or wetting her pants, petitioner responded:

> Wow, I was all of that, you know. I couldn't get to the bathroom on time. I was having to go frequently, frequently, frequently. And, of course, I aided the issue by drinking a lot, but my stomach and mouth were on fire, so I had a lot to drink. So I kept drinking because I – my stomach was upset. So, yes, I had to go to the bathroom frequently.

Tr. 39.

[63] Douglas A. Kerr & Harold Ayetey, *Immunopathogenesis of Acute Transverse Myelitis*, 15 CURRENT OPINION IN NEUROLOGY 339, 339-40 (2002).

[64] Petitioner had 12 ESIs between December 22, 2009 and December 19, 2014. *See generally* Pet. Ex. 6.

[65] Though at hearing, petitioner denied recent history of diverticulitis. Tr. 40-41.

On Tuesday, October 15, 2013, petitioner reported to Dr. Khamishon with new onset of weakness in the lower extremities and bowel and bladder incontinence "since four days ago." Pet. Ex. 2 at 1-4. Petitioner explained to Dr. Khamishon that four days ago, Friday night she could not stop going with diarrhea and urinating "and could not control it", but that morning, October 15, 2013 was the opposite, she felt like she had to urinate but couldn't. Tr. 18.

Dr. Marco testified that he provided Dr. Khamishon with petitioner's medical history and the events of Sunday night in which she had a bowel movement but was unaware of it. "[w]hen we looked in her underwear on Sunday – Sunday night, her underwear was wet as well." Tr. 61. According to Dr. Marco, she certainly had bowel incontinence and he felt she had "some urinary incontinence as well on October 13th." Tr. 73-74.

In the letter petitioner submitted after the hearing, she stated:

> [I] brought up my experience with diarrhea and running to urinate before I leaked on that Friday and Saturday morning to compare and contrast with the incontinence on Sunday and then on Wednesday that also caused leakage but was just the opposite – my stool was not diarrhea but just hard…--a total contrast of just a few days earlier.

ECF No. 44 at 5-6.

Upon presentation to the emergency room at Sharp on Wednesday, October 16, 2013, petitioner reported to Dr. Roth the presence of chronic complaints and neuropathies over the years and a loss of bladder and bowel function since Thursday and walking more irregularly. Pet. Ex. 3 at 109.

On Friday, October 18, 2013, during a urological consult, petitioner reported that eight hours after Crestor, which she had taken one week ago,[66] she had total urinary and rectal incontinence. Since then she has developed numbness and paresthesias to the perianal area. She had been wearing pads and had been using the bathroom once an hour but had no sensation of feeling full, empty, or of the urine coming out. Pet. Ex. 3 at 121-22.

At the time of her MRI on Friday, October 18, 2013, she reported that she had weakness in her hips and left foot and had been "very unsteady since last Thursday,"[67] with dizziness when putting her head down and leaning over. Pet. Ex. 3 at 88.

By petitioner's own admission, the onset of her inability to control her bladder (and potentially her bowels) started on the evening of October 11, 2013 and into the morning hours of October 12, 2013. Petitioner described her development of diarrhea with frequent urination blaming that event on spicy food and water intake. Despite the amount of water petitioner drank, she admitted multiple times and in different contexts that she was unable to control her urination

[66] That would be October 11, 2013.

[67] "Last Thursday" would be October 10, 2013, the day before the allegedly causal flu vaccine.

that night/early morning. Her loss of bladder control was followed by bowel, and potentially bladder incontinence, on the evening of Sunday, October 13, 2013, according to Dr. Marco. Tr. 61, 73-74. She then developed weakness and pain in her lower extremities on Monday, October 14, 2013, which became more profound with urinary incontinence on Tuesday, October 15, 2013. By Wednesday, October 16, 2013, she was hospitalized with further weakness and numbness that extended to her perineal area, extreme pain, and bowel and bladder incontinence requiring catheterization.

The petitioner and her family blame the inconsistencies between the affidavits, testimony, and medical records on petitioner being heavily medicated in the emergency room for her pain, resulting in her poor recollection and providing inaccurate facts. In her letter to me, she blamed the inaccuracies on her level of pain. ECF No. 44. However, the various doctors who saw her from the emergency room through the first several days of admission documented her as alert and oriented, with normal recent and remote memory, language, and fund of knowledge. Her speech was fluent and comprehensive. Pet. Ex. 3 at 128-29. She was resting comfortably in bed, and her affect was "quite reasonable." Pet. Ex. 2 at 126. The hospital record further documents that petitioner was given .05 mg. of Dilaudid[68] about an hour after her arrival to the emergency room and after she was examined. Pet. Ex. 3 at 22, 24, 53. The Medication Administration Record following admission documents Tramadol given every six hours for pain, a pain medication that petitioner routinely used for chronic pain on a daily basis. *Id*. at 28. The medical record further documents that petitioner was treated only with IV steroids for possible TM.[69] Later, during her hospitalization, she developed acute perforated diverticulitis and underwent IR drainage and NG tube placement for feeding to allow the diverticulitis to calm down. It was at that time, on October 25, 2013, that morphine was started due to worsening abdominal complaints. *Id*. at 25-31, 107. The hospital records note that petitioner was confused for the first time on October 28, 2013, after several days of morphine. *Id*. at 76.

There are many discrepancies and inconsistencies in the record regarding other issues to be addressed at a later time. This ruling is on onset only and on that issue, one thing is for certain: petitioner's inability to hold urine and loss of bladder control, began the evening of October 11, 2013, and her symptomology then progressed, resulting in her hospitalization on October 16, 2013.

V. Conclusion

Upon careful review of the record, I find that the onset of petitioner's symptoms began with the loss of bladder control in the late evening of October 11, 2013, the same day as her influenza vaccine. Petitioner has already filed two expert reports from Dr. Lawrence Steinman; however, these reports were based on the facts as provided by petitioner. Petitioner is to file an

[68] Dilaudid, or hydromorphone hydrochloride, is a drug for the relief of moderate pain and severe pain with a higher rapid onset compared to morphine. *Hydromorphone Hydrochloride – Drug Summary*, PRESCRIBERS' DIGITAL REFERENCE, http://www.pdr.net/drug-summary/Dilaudid-Injection-and-HP-Injection-hydromorphone-hydrochloride-490 (last visited Jul. 12, 2018).

[69] Notably, petitioner's affidavit submitted in May of 2016 also notes that she was treated with IV steroids. Pet. Ex. 12 at 2.

expert report from Dr. Steinman which relies on the timing of onset as found in this Ruling. All experts in this case, are to rely on the timing of onset as found in this Ruling.

Accordingly, the following is ORDERED:

By Monday, October 1, 2018, petitioner shall file either an expert report that is based on the facts as found herein, or a status report indicating how she intends to proceed. Petitioner shall provide a copy of this Onset Ruling to each of her expert witnesses, and her expert(s) shall rely on the timing of onset as I have found it in this Ruling. If petitioner is unable to secure reports from her expert(s) based on the timing of onset as I have found it, she shall file either a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record, all of which will result in the dismissal of her claim.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master